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Long-term follow-up after transoral outlet reduction following Roux-en-Y gastric bypass: Back to stage 0?

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ABSTRACT

Background and study aims Significant weight regain affects up to one-third of patients after Roux-en-Y gastric bypass (RYGB) and demands treatment. Transoral outlet reduction (TORe) with argon plasma coagulation (APC) alone or APC plus full-thickness suturing TORe (APC-FTS) is effective in the short term. However, no study has investigated the course of gastrojejunostomy (GJ) or quality of life (QOL) data after the first post-procedure year.

Patients and methods Patients eligible for a 36-month follow-up visit after TORe underwent upper gastrointestinal endoscopy with measurement of the GJ and answered QOL questionnaires (RAND-36). The primary aim was to evaluate the long-term outcomes of TORe, including weight loss, QOL, and GJ anastomosis (GJA) size. Comparisons between APC and APC-FTS TORe were a secondary aim.

Results Among 39 eligible patients, 29 returned for the 3-year follow-up visit. There were no significant differences in demographics between APC and APC-FTS TORe groups. At 3 years, patients from both groups regained all the weight lost at 12 months, and the GJ diameter was similar to the pre-procedure assessment. As to QOL, most improvements seen at 12 months were lost at 3 years, returning to pre-procedure levels. Only the energy/fatigue domain improvement was kept between the 1- and 3-year visits.

Conclusions Obesity is a chronic relapsing disease. Most effects of TORe are lost at 3 years, and redilation of the GJA occurs. Therefore, TORe should be considered iterative rather than a one-off procedure.

Introduction

Sound data support bariatric surgery as the gold-standard treatment for refractory moderate and severe obesity [1,2]. Roux-en-Y gastric bypass (RYGB) is one of the most effective techniques for weight loss and the most performed bariatric surgery in many parts of the world [1,3]. However, up to one-third of patients suffer from weight regain in the long term [4], which is related to comorbid recidivism and diminished quality of life (QOL) [5].

While surgical revisions and conversions are risky [6], endoscopic treatment by reducing the gastrojejunal anastomosis (transoral outlet reduction) (TORe) size is effective and safer in the short term [7–11]. Recent studies showed that argon plasma coagulation (APC) alone and APC plus full-thickness suturing TORe (APC-FTS) are similarly effective for this purpose [7, 8].

Nevertheless, long-term data are scarce. Jirapinyo et al published a retrospective study describing clinical outcomes of sutured-TORe at 5 years [11]. Three hundred and thirty-one pa-

tients were included at baseline, and the authors reported that most of the weight lost at 12 months was maintained at 60 months. However, only 102 individuals had 5-year data available, and about one-third of the sample received additional weight loss therapies during follow-up. Similarly, Callahan et al. [12] reported 60-month clinical outcomes from 70 patients undergoing TORe. Contrary to Jirapinyo et al's results, this group reported that, on average, patients regained weight after the 6-month nadir. Unfortunately, Callahan et al. did not disclose the use of adjunct weight loss methods or data on the resolution rates of the gastrogastric fistulas.

To date, no study has investigated the course of the gastrojejunostomy after the first post-procedure year. Similarly, there are no long-term data on QOL or the post-procedure weight loss journey with a standardized follow-up approach. We aimed to fill this gap by evaluating 3-year clinical and endoscopic outcomes after TORe.

Patients and methods

Study design and registry

This single-center study included patients from a previous open-label randomized controlled trial (RCT) comparing APC to APC-FTS TORe [7]. The initial RCT was registered in the clinicaltrials.gov database (NCT03094936), and this extended follow-up study was approved by the University of Sao Paulo Institutional Review Board (protocol number 5.284.051).

Eligibility criteria

Adult patients with a history of RYGB at least 2 years beforehand who presented significant weight regain (>20 % of the lost weight at the nadir) and with a gastrojejunostomy anastomosis (GJA) ≥15 mm were eligible for the initial trial. We excluded patients with coagulopathies, gastrogastric fistulas, and severe esophagitis. The patients were allocated to APC or APC-FTS groups in a 1:1 ratio during the initial trial using sealed opaque envelopes. The procedures took place between October 2017 and July 2018 [7]. After the 12-month follow-up research visit, the patients were followed clinically in our institution. Individuals returning for the 3-year visit were considered eligible for the present study.

Procedures

Patients were under general anesthesia for the index procedure and received prophylactic antibiotics. Per protocol, we extended the APC ablation 2 cm and 1 cm proximally in the APC and APC-FTS groups, respectively. We employed the Apollo Overstitch device (Apollo Endosurgery, Austin, Texas, United States) to place sutures in a modified figure-of-8 pattern for the suturing group. The full description of the technique was published elsewhere [7]. Technical success was defined as GJA ≤12 mm at the end of the procedure for the APC-FTS group and at the follow-up endoscopy for the APC group. Patients in the latter group received additional ablation sessions every 6 weeks until the stoma size reached 12 mm or up to a maximum of three sessions as per previous literature [13]. To avoid interobserver disagreement, the same operator assessed all GJA diameters using standard foreign body forceps per literature recommendation [14].

Follow-up regimen

After the intervention, patients were followed clinically per our institution' s protocol. In our institution, bariatric surgeons follow patients every 6 months after the first post-procedure year. However, because our patients received their intervention between 2017 and 2018, the standard follow-up after 12 months was hindered by the COVID-19 pandemic. During 2020 and early 2021, all non-urgent in-person visits were canceled in our institution per local regulations, and our patients were not followed as usual.

After the COVID-19 pandemic restrictions were partially lifted, patients eligible for a 36-month follow-up visit were contacted via phone and summoned for an in-person visit. Patients answered QOL questionnaires (RAND-36) and had their body weight reviewed. Moreover, they underwent an esophagogastroduodenoscopy (EGD) with GJA measurement.

Outcomes and aims

Our primary aim was to evaluate the long-term outcomes of TORe. The primary endpoint was % total weight loss (%TWL) at 3 years, defined as [(follow-up weight – preprocedural weight) *100/preprocedural weight]. Secondary outcomes included the diameter of the GJA (mm) and QOL scores assessed with the RAND-36 questionnaire [15]. As a secondary aim, we planned a comparison between APC alone and APC-FTS TORe.

Statistical analysis

We ran comparisons within groups between different time points and groups. Medians and interquartile ranges were reported for continuous variables, and the Mann-Whitney U test and Wilcoxon signed-rank for paired samples were used for correlations. We reported the numbers and valid percentages for categorical variables, and the Chi-square and Fisher's tests were used to test for correlation according to the expected counts. The Statistical Package for Social Sciences (SPSS), version 28.0 (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Armonk, New York, United States) was used for data entry, management, and analyses. $P<0.05$ was considered significant for a 95 % CI.

Results

Among 39 eligible patients, 29 returned for the 3-year follow-up visit (74 % follow-up rate). None of them had had in-person visits between the 12-month and the 3-year visits. Before TORe, patients had a median age, weight, and body mass index of 42 years old (37–51), 107 kg (100–129.4), and 43.1 kg/m^2 (36.8–46.7), respectively. There were no significant differences in demographics between APC and APC-TORe patients. No patient received additional weight loss treatments other than clinical follow-up. ▶ **Table 1** summarizes demographic data for the whole sample and each group.

At 6 months, the enrolled patients presented a median of 10.8 % TWL (6.2–14.2) and 26.0 (15.6–42.2) % estimated

▶ **Table 1** Demographic and weight loss data for the included patients.

	All patients N = 29	APC N = 15	FTS-APC N = 14	*P* value
Age[1] (yr)	42 (37–51)	42 (37–59)	45 (35.5–50.3)	0.561
Female gender[2] n (%)	25 (86.2)	13 (86.7)	12 (85.7)	1.000
Years after surgery[1] (yr)	6 (5.0–10.5)	9 (5.0–11.0)	6 (4.8–7.3)	0.158
Height[1] (cm)	163 (158–171)	163 (156–165)	166.5 (159.5–173.3)	0.331
Preoperative BMI[1] (kg/m^2)	49.5 (12.2–58.1)	49.3 (41.4–55.2)	53.4 (45.6–59.0)	0.270
Nadir weight[1] (kg)	80 (75–92)	78 (74–86)	85.5 (75–100.3)	0.290
Absolute weight loss from surgery to nadir[1] (kg)	50.5 (36.5–65)	41 (31.9–61)	55.3 (40.0–68.8)	0.201
Nadir BMI[1] (kg/m^2)	31.1 (28.1–35.5)	30.9 (27.1–34.6)	31.5 (28.5–37.3)	0.621
Preprocedural weight[1] (kg)	107 (100–129.4)	105.7 (91.2–131.7)	108.5 (100.4–132)	0.591
Regained weight[1] (kg)	22.8 (18.1–33.4)	27 (19.2–37)	21 (13.1–30.3)	0.290
Preprocedural BMI[1] (kg/m^2)	43.1 (36.8–46.7)	43.4 (35.3–44.9)	40.9 (37.5–49.8)	0.591
Preprocedural endoscopic pouch length[1] (cm)	5 (4–6)	5 (4–6)	5 (4–6)	0.983
Preprocedural GJA diameter[1] (mm)	20 (18–23.5)	20 (18–22)	20 (18–26.3)	0.561
Obesity-related comorbidities (pre-TORe) n (%)				
▪ Hypertension[3]	11 (37.9)	6 (40.0%)	5 (35.7)	0.812
▪ Non-insulin-dependent diabetes[2]	3 (10.3)	3 (20.0%)	0 (0)	0.224
▪ Venous disease[2]	3 (10.3)	2 (13.3)	1 (7.1)	1.000
▪ Osteoarthritis[2]	4 (13.8)	3 (20.0)	1 (7.1)	0.598
▪ Dyslipidemia[2]	1 (3.4)	1 (6.7)	0 (0)	1.000
▪ Endocrine comorbidities[2]	4 (13.8)	2 (13.3)	2 (14.3)	1.000

APC, Argon plasma coagulation; FTS-APC, argon plasma coagulation plus full-thickness endoscopic suturing; BMI, body mass index; TORe: transoral outlet reduction.
[1] Mann-Whitney U test.
[2] Fisher's test.
[3] Chi-square test.

weight loss (EWL). At 12 months, there was a minor overall weight gain, with median EWL and TWL of 22.9% (9.0–31.2) and 8.2% (4.2–12.5), respectively. At 3 years, patients regained all the weight lost at 12 months, returning approximately to their pre-procedure weight. There was no difference in outcomes comparing patients from the APC and APC-FTS groups. ▶ **Table 2** summarizes weight loss outcomes.

Endoscopic follow-up at 3 years revealed that the median diameter of the GJA was 22 mm, 22 mm, and 24 mm for the whole sample, APC, and APC-FTS group, respectively. Those values are similar to pre-procedure ones, suggesting redilation over time. ▶ **Table 3** summarizes data regarding the diameter of the GJA. ▶ **Fig. 1** shows the aspect of the GJA for patients from different groups at baseline, after TORe, and at 3 years.

As to QOL, patients showed improvements in physical functioning, energy/fatigue, emotional well-being, and general health domains at 12 months compared to baseline (▶ **Fig. 1**). At 3 years, all improvements except energy/fatigue were lost, reaching pre-procedure scores. Although the median values for all domain scores were similar between groups at baseline, 1, and 3 years, APC patients experienced a significant improvement in energy/fatigue at 3 years compared to baseline, while APC-FTS patients did not. ▶ **Table 4** summarizes data and comparisons concerning the QOL.

Discussion

This is the first study to investigate the natural history of GJA after TORe in the long term. Also, no study has reported QOL data after the first post-procedure year. Although there are non-controlled articles reporting 3- and 5-year outcomes of TORe, they are mostly restricted to clinical outcomes [16] and are associated with several confounding variables, such as including patients with gastrogastric fistulas [12] or with concurrent weight loss methods (pharmacotherapy, additional TORe sessions, surgery) [11].

In addition, our patients were not followed as they should have been due to the restrictions posed by the COVID-19 pan-

▶ **Table 2** Weight loss outcomes and comparisons between groups.

	All patients N = 29	APC N = 15	APC-FTS N = 14	*P* value (APC vs. APC-FTS)
6-month				
▪ %EWL[1]	26.0 (15.6–42.2)	31.4 (18.7–44.0)	19.5 (9.3–34.0)	0.191
▪ %TWL[1]	10.8 (6.2–14.2)	13.1 (8.4–14.3)	8.4 (3.6–14.2)	0.228
▪ BMI reduction[1]	4.0 (2.4–6.1)	5.2 (3.3–6.1)	3.3 (1.5–6.2)	0.209
12-month				
▪ %EWL[1]	22.9 (9.0–31.2)	24.3 (12.6–32.4)	13.8 (2.0–32.3)	0.256
▪ %TWL[1]	8.2 (4.2–12.5)	8.3 (6.2–13.0)	5.5 (0.9 –10.9)	0.206
▪ BMI reduction[1]	3.1 (1.9–4.8)	3.6 (2.7–4.8)	2.1 (0.4–4.5)	0.206
3-year				
▪ %EWL[1]	–3.4 (–10.1–15.4)	2.5 (–8.7–15.4)	–6.3 (–19.7–13.4)	0.206
▪ %TWL[1]	–4.4 (–4.3–3.9)	0.7 (–2.5–6.7)	–2.3 (–8.4–2.7)	0.176
▪ BMI reduction[1]	–0.6 (–2.0–1.5)	0.2 (–1.2–2.9)	–1.0 (–3.7–0.9)	0.222

APC, Argon plasma coagulation; FTS-APC, argon plasma coagulation plus full-thickness endoscopic suturing; EWL, excess weight loss; TWL, total weight loss; BMI, body mass index.
[1] Mann-Whitney U test.

▶ **Table 3** Diameter of the gastrojejunal anastomosis.

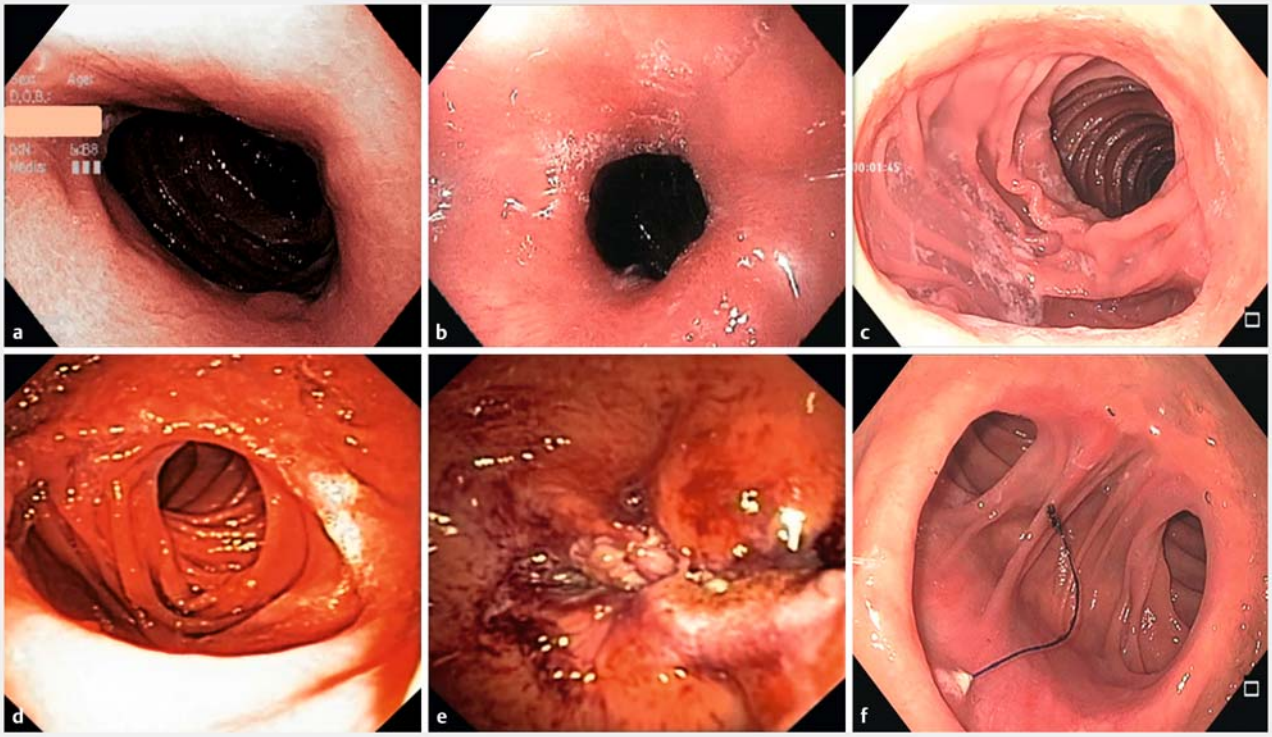
	All patients N = 29	APC N = 15	FTS-APC N = 14	*P* value
Endoscopic anastomosis diameter at baseline	20 (18–25)	20 (18–25)	20 (18–26.3)	0.876
Endoscopic anastomosis diameter at 3 years	22 (18–25)	22 (18–25)	24 (19.5–30)	0.242
Delta	2 (–2–5)	0 (–6–4)	2.5 (0–7)	0.136

APC, Argon plasma coagulation; FTS-APC, argon plasma coagulation plus full-thickness endoscopic suturing.

demic. On the one hand, this fact probably worsened our patients' outcomes and adds to the pandemic as a risk factor for weight gain [17, 18]. On the other hand, it provides raw, pure data depicting the natural history of body weight, QOL, and GJA if no adjunct therapy and an irregular follow-up regimen are implemented. This is critical and allows for a more precise understanding of weight regain as a condition and how to address it adequately.

Regarding weight loss, we demonstrated that patients regained all their lost weight at 3 years and that APC and APC-FTS patients presented similar behaviors. Our data contradict previous literature that shows that part of the weight loss is kept in the long term [9, 11, 12, 16]. Several factors may explain such a discrepancy. First, the COVID-19 pandemic affected our routine follow-up, which is critical to retain weight [19], and has been proven to increase the risk of weight gain [17, 18]. None of the previous studies included data collected during the pandemic. Another factor is the absence of concurrent therapies. Our patients did not receive any additional weight loss therapies during follow-up. Previous studies either acknowledge using adjunct methods [11] or do not mention it at all, meaning that it was not a controlled variable [9, 12, 16]. Together, those aspects could explain why our weight loss results are worse than previously published data.

QOL parameters echoed the weight trends, worsening throughout follow-up and reaching pre-procedure levels. This is expected as previous literature demonstrates that weight regain is closely associated with deteriorated QOL [5, 20]. The APC group, however, retained some of the improvement in the energy/fatigue scores and drove the whole-sample improvement compared to the baseline. It is unclear why there was such a distinction between groups, considering the similar weight loss at 3 years. We speculate that the minor difference in %EWL and %TWL at 3 years was insufficient to reach statistical difference due to the small sample size (type 2 error). Nonetheless, it was enough to translate into a benefit concerning the QOL. This fact demonstrates how the self-perception of weight amplifies and reflects on other aspects of patients' lives. Ultimately, our results create another piece of evidence to tighten the link between QOL and weight loss.



▶ **Fig. 1** Endoscopic aspect of the gastrojejunal anastomosis. **a** Pre-procedure aspect of an APC group patient. **b** Follow-up endoscopy at 6 weeks. **c** Follow-up endoscopy at 3 years. **d** Pre-procedure aspect of an APC-FTS group patient. **e** Immediate postprocedure aspect of the GJA. **f** Follow-up endoscopy at 3 years.

Along with body weight and QOL, the mean diameter of the GJA also returned to the baseline value. These data are unique and prove that redilation after TORe occurs over time. Currently, TORe as a procedure relies on the assumption that dilation may occur after surgery and that patients lose pouch retention and prolonged satiety. However, no study has investigated the natural history of GJA diameter over time after surgery. The assumption was based on a combination of two different factors. First, most surgeons calibrate the stoma size using standardized Fouchet bougies or circular staplers [21, 22]. Therefore, patients are discharged from surgery with small and standardized GJAs. Second, patients present with diverse stoma sizes, and larger ones are associated with higher rates of weight regain in the long term [23, 24]. Still, no currently available study has a longitudinal design. Our results prove that dilation occurred from TORe to follow-up and indirectly support that it may also happen from surgery to TORe. This information supports the previous assumption, making it more tangible.

Aside from the physiology and natural history perspective, redilation of the GJA precipitates another discussion concerning the current follow-up strategy. Most centers implement a multidisciplinary approach to address weight regain and to assist patients in maintaining their weight loss [14, 25]. However, neither a standardized endoscopic follow-up nor well-defined criteria currently exist to indicate reTORe. Considering our results, it seems reasonable to include a routine endoscopic follow-up with measurements of GJA diameter. Additional TORe could be indicated considering clinical (weight regain) and endoscopic (redilation) features, aiming to sustain weight loss and improve metabolic and QOL in the long term. Ultimately, TORe should be considered iterative rather than a one-off procedure.

Our study was not free from limitations. First, our sample size was small and highly specific. We acknowledge this limitation and that further larger studies are still needed. Second, we do not have data for the time period from immediately postprocedure to the 3-year assessments. Thus, we cannot determine when exactly redilation occurs or when it reaches a critical or a turning point. Additional studies could address this limitation by including yearly endoscopic follow-up and correlating it with weight loss. Still, our results helped by proving that this interval is undoubtedly shorter than 3 years. Finally, the COVID pandemic could also have directly affected QOL, adding to weight regain as a QOL-deteriorating factor.

Conclusions

In conclusion, obesity is a chronic, relapsing disease. As such, most effects of TORe are lost at 3 years, and redilation of the GJA occurs. Except for a slight improvement in energy/fatigue, there was no difference between APC and APC-TORe. Our data

▶ **Table 4** RAND-36 scores for quality of life for the whole sample and according to the allocation groups.

	All patients	APC	APC-FTS	*P* value for
	N = 29	N = 15	N = 14	APC vs. APC-FTS
A. Physical functioning				
▪ Baseline	50 (27.5–75)	40 (30–65)	57.5 (25–77.5)	0.370
▪ 1-year follow-up	75 (45–90)	75 (45–90)	72.5 (42.5–100)	0.871
▪ 3-year follow-up	50 (26.3–70)	55 (25–70)	45 (27.5–72.5)	0.991
▪ *P* value for baseline vs. 1 year[1]	< 0.001	0.003	0.034	
▪ *P* value for baseline vs. 3 years[1]	0.900	0.457	0.447	
▪ *P* value for 1 year vs. 3 years[1]	0.002	0.032	0.070	
B. Role limitations due to physical health				
▪ Baseline	50 (0–87.5)	0 (0–75)	75 (25–100)	0.152
▪ 1-year follow-up	75 (37.5–100)	50 (25–100)	75 (37.5–100)	0.560
▪ 3-year follow-up	50 (26.3–70)	50 (0–100)	25 (0–100)	0.800
▪ *P* value for baseline vs. 1 year[1]	0.099	0.078	0.617	
▪ *P* value for baseline vs. 3 years[1]	0.926	0.453	0.373	
▪ *P* value for 1 year vs. 3 years[1]	0.124	0.406	0.281	
C. Role limitations due to emotional problems				
▪ Baseline	33.3 (0–100)	33.3 (0–100)	50 (0–100)	0.829
▪ 1-year follow-up	66.7 (0–100)	33.3 (0–100)	66.7 (0–100)	0.603
▪ 3-year follow-up	16.7 (0–66.7)	33.3 (0–66.7)	0 (0–83.3)	0.990
▪ *P* value for baseline vs. 1 year[1]	0.875	1.000	0.844	
▪ *P* value for baseline vs. 3 years[1]	0.089	0.328	0.250	
▪ *P* value for 1 year vs. 3 years[1]	0.092	0.305	0.281	
D. Energy/fatigue				
▪ Baseline	35 (25–60)	35 (20–40)	47.5 (28.8–66.3)	0.108
▪ 1-year follow-up	50 (40–67.5)	45 (40–50)	65 (45–81.3)	0.021
▪ 3-year follow-up	47.5 (35–58.8)	45 (30–50)	50 (37.5–67.5)	0.080
▪ *P* value for baseline vs. 1 year[1]	< 0.001	0.20	0.012	
▪ *P* value for baseline vs. 3 years[1]	0.004	0.011	0.103	
▪ *P* value for 1 year vs. 3 years[1]	0.240	0.433	0.419	
E. Emotional well-being				
▪ Baseline	56 (40–78)	52 (35–64)	62 (47–88)	0.154
▪ 1-year follow-up	72 (42–83.3)	72 (40–80)	76 (47–87)	0.523
▪ 3-year follow-up	56 (44–74	56 (36–76)	56 (44–68)	0.901
▪ *P* value for baseline vs. 1 year[1]	0.024	0.006	0.625	
▪ *P* value for baseline vs. 3 years[1]	0.762	0.100	0.530	
▪ *P* value for 1 year vs. 3 years[1]	0.026	0.083	0.129	
F. Social functioning				
▪ Baseline	62.5 (37.5–87.5)	50 (37.5–75)	87.5 (40.6–100)	0.072
▪ 1-year follow-up	75 (37.5–87.5)	75 (25–87.5)	75 (46.9–90.6)	0.886

▶ **Table 4** (Continuation)

	All patients	APC	APC-FTS	*P* value for
	N = 29	N = 15	N = 14	APC vs. APC-FTS
▪ 3-year follow-up	56 (44–74)	50 (37.5–75)	62.5 (25–93.8)	0.389
▪ *P* value for baseline vs. 1 year[1]	0.355	0.161	0.775	
▪ *P* value for baseline vs. 3 years[1]	0.673	0.844	0.453	
▪ *P* value for 1 year vs. 3 years[1]	0.115	0.081	0.648	
G. Pain				
▪ Baseline	45 (22.5–67.5)	40 (20–57.5)	55 (22.5–77.5)	0.153
▪ 1-year follow-up	57.5 (28.8–72.5)	45 (22.5–67.5)	66.3 (42.5–88.1)	0.085
▪ 3-year follow-up	45 (25–57.5)	45 (22.5–55)	45 (32.5–78.8)	0.143
▪ *P* value for baseline vs. 1 year[1]	0.053	0.082	0.303	
▪ *P* value for baseline vs. 3 years[1]	0.736	0.814	0.528	
▪ *P* value for 1 year vs. 3 years[1]	0.007	0.014	0.138	
H. General health				
▪ Baseline	45 (30–57.5)	40 (30–55)	47.5 (37.5–72.5)	0.380
▪ 1-year follow-up	60 (42.5–75)	60 (40–75)	52.5 (43.8–76.3)	0.754
▪ 3-year follow-up	40 (30–60)	40 (20–50)	50 (35–67.5)	0.080
▪ *P* value for baseline vs. 1 year[1]	0.004	0.002	0.311	
▪ *P* value for baseline vs. 3 years[1]	0.477	0.330	0.951	
▪ *P* value for 1 year vs. 3 years[1]	< 0.001	< 0.001	0.208	

APC, argon plasma coagulation; FTS-APC, argon plasma coagulation plus full-thickness endoscopic suturing.
[1] Wilcoxon signed-rank for paired samples.

suggest that TORe should be considered an iterative rather than one-off procedure.

Competing interests

Vitor Brunaldi: received payments for lectures and testimonials from Erbe Elektromedizin Gmbh. Diogo T. H. de Moura: Advisory board for Bariatek Solutions. Eduardo G. H. de Moura: Speaker for Boston Scientific and Olympus. All other authors disclose no conflicts of interest.

Clinical trial

ClinicalTrials.gov (http://www.clinicaltrials.gov/)
NCT03094936
TRIAL REGISTRATION: Extended follow-up study for a RCT NCT03094936 at ClinicalTrials.gov

References

[1] Carlsson LMS, Sjöholm K, Jacobson P et al. Life expectancy after bariatric surgery in the Swedish Obese Subjects Study. N Engl J Med 2020; 383: 1535–1543

[2] Eisenberg D, Shikora SA, Aarts E et al. 2022 American Society for Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO): Indications for metabolic and bariatric surgery. Surg Obes Relat Dis 2022; 18: 1345–1356

[3] Angrisani L, Santonicola A, Iovino P et al. Bariatric surgery survey 2018: Similarities and disparities among the 5 IFSO chapters. Obes Surg 2021; 31: 1937–1948

[4] Cooper TC, Simmons EB, Webb K et al. Trends in weight regain following Roux-en-Y gastric bypass (RYGB) bariatric surgery. Obes Surg 2015; 25: 1474–1481

[5] Jirapinyo P, Abu Dayyeh BK, Thompson CC. Weight regain after Roux-en-Y gastric bypass has a large negative impact on the Bariatric Quality of Life Index. BMJ Open Gastroenterol 2017; 4: e000153–e000153

[6] Kuzminov A, Palmer AJ, Wilkinson S et al. Re-operations after secondary bariatric surgery: a systematic review. Obes Surg 2016; 26: 2237–2247

[7] Brunaldi VO, Farias GFA, de Rezende DT et al. Argon plasma coagulation alone versus argon plasma coagulation plus full-thickness endoscopic suturing to treat weight regain after Roux-en-Y gastric bypass: a prospective randomized trial (with videos). Gastrointest Endosc 2020; 92: 97–107.e105

[8] Jaruvongvanich V, Vantanasiri K, Laoveeravat P et al. Endoscopic full-thickness suturing plus argon plasma mucosal coagulation versus argon plasma mucosal coagulation alone for weight regain after gastric bypass: a systematic review and meta-analysis. Gastrointest Endosc 2020; 92: 1164–1175.e1166

[9] Moon RC, Teixeira AF, Neto MG et al. Efficacy of utilizing argon plasma coagulation for weight regain in Roux-en-Y gastric bypass patients: a multi-center study. Obesity Surg 2018; 28: 2737–2744

[10] Brunaldi VO, Jirapinyo P, de Moura DTH et al. Endoscopic treatment of weight regain following Roux-en-Y gastric bypass: a systematic review and meta-analysis. Obes Surg 2018; 28: 266–276

[11] Jirapinyo P, Kumar N, AlSamman MA et al. Five-year outcomes of transoral outlet reduction for the treatment of weight regain after Roux-en-Y gastric bypass. Gastrointest Endosc 2020; 91: 1067–1073

[12] Callahan ZM, Su B, Kuchta K et al. Five-year results of endoscopic gastrojejunostomy revision (transoral outlet reduction) for weight gain after gastric bypass. Surg Endosc 2019; 34: 2164–2171

[13] Baretta GAP, Alhinho HCAW, Matias JEF et al. Argon plasma coagulation of gastrojejunal anastomosis for weight regain after gastric bypass. Obes Surg 2015; 25: 72–79

[14] Galvao Neto M, Brunaldi VO, Grecco E et al. Good clinical practices on argon plasma coagulation treatment for weight regain associated with dilated gastrojejunostomy following Roux-en-Y gastric bypass: a Brazilian-modified delphi consensus. Obes Surg 2022; 32: 273–283

[15] Hays RD, Sherbourne CD, Mazel RM. The RAND 36-Item Health Survey 1.0. Health economics 1993; 2: 217–227

[16] Kumar N, Thompson CC. Transoral outlet reduction for weight regain after gastric bypass: long-term follow-up. Gastrointest Endosc 2016; 83: 776–779

[17] Zeigler Z. COVID-19 self-quarantine and weight gain risk factors in adults. Curr Obes Rep 2021; 10: 423–433

[18] Chang TH, Chen YC, Chen WY et al. Weight gain associated with COVID-19 lockdown in children and adolescents: a systematic review and meta-analysis. Nutrients 2021; 13: 3668

[19] Yanos BR, Saules KK, Schuh LM et al. Predictors of lowest weight and long-term weight regain among Roux-en-Y gastric bypass patients. Obes Surg 2015; 25: 1364–1370

[20] Bauraitė K, Mikuckytė D, Gudaitytė R et al. Factors associated with quality of life and weight regain 12 years after Roux-en-Y gastric bypass. Surg Endosc 2022; 36: 4333–4341

[21] Smith C, Garren M, Gould J. Impact of gastrojejunostomy diameter on long-term weight loss following laparoscopic gastric bypass: a follow-up study. Surg Endosc 2011; 25: 2164–2167

[22] Sampaio-Neto J, Branco-Filho AJ, Nassif LS et al. Complications related to gastric bypass performed with different gastrojejunal diameters. Arq Bras Cir Dig 2016; 29: 12–14

[23] Abu Dayyeh BK, Lautz DB, Thompson CC. Gastrojejunal stoma diameter predicts weight regain after Roux-en-Y gastric bypass. Clin Gastroenterol Hep 2011; 9: 228–233

[24] Abu Dayyeh BK, Jirapinyo P, Thompson CC. Plasma ghrelin levels and weight regain after Roux-en-Y gastric bypass surgery. Obes Surg 2017; 27: 1031–1036

[25] Cambi MPC, Baretta GAP, Magro DO et al. Multidisciplinary approach for weight regain-how to manage this challenging condition: an expert review. Obes Surg 2021; 31: 1290–1303